

## REMARKS

Claims 1-14 and 19-20 are withdrawn by the applicant from this application. Claims 15-18 and 21-25 remain pending in the application. In the Office Action mailed March 3, 2004, claim 16 stands rejected under 35 U.S.C. 112, second paragraph. Claims 15 and 21-25 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,543,449 (Woodring et al). Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al in view of U.S. Pat. No. 5,931,960 (Gilmore et al). Claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al in view of U.S. Pat. No. 6,024,089 (Wallace et al). Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al in view of known techniques in the art of the invention.

### I. Rejections under 35 U.S.C. 102(e)

Claims 15 and 21-25 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,543,449 (Woodring et al). The applicant respectfully disagrees with the Examiner's position that Woodring et al, or any other prior art, anticipates the applicant's invention.

The applicant's invention is a multi-dimensional relational display that relates and displays patient and ventilator data in a way that provides information to the user that is not available from the raw data alone, in order to improve the user's interpretation and use of the data (published app., para. 0026). It displays the information, and the relationships between the information, in a manner that minimizes the cognitive steps that must be performed by the user in order to interpret the data and, if necessary, to know what corrective actions should be taken, thus reducing the incidence and likelihood of human error. In essence, the applicant's invention allows equipment to better communicate with health care providers by having the equipment displays map onto the "natural language" used by the providers. This type of display has been defined by the applicant as a "medical process diagram" or "object display" (published app., para. 0028). These types of displays are also referred to in the art as "ecological interface displays" or "emergent feature displays". In general, the success of medical process diagrams is a function of how well the user's cognitive needs are illustrated and mapped into the graphical elements of the display (published app., para. 0029).

In particular, the object display of the applicant's invention accomplishes this goal by utilizing visual memory cues, intuitive graphical representations, and/or perceptual diagrams in

order to map complex data (published app., para. 0031), rather than by using the earlier generation alphanumeric or signal waveform representations of ventilator and/or patient parameters that are seen in such displays as those disclosed by Woodring et al. By mapping the raw data onto the display in the manner of the applicant's invention, new shapes are created that have independent meaning. These shapes give health care providers a direct connection to the state of the patient, allowing them to quickly and effectively monitor a patient's condition, to recognize problems when they occur, to identify the cause of the problems, and to rapidly identify and take corrective action.

The system of the invention was developed by understanding and describing the mental models that medical doctors use when thinking about the physiological aspects of the processes being displayed and how they use this mental model to diagnose pathological states and subsequently take appropriate corrective action for their patients (published app., para. 0029). The object displays of the applicant's invention specifically present: 1) the relationships of certain data to other data; 2) data in context; 3) the relationship of certain data to a frame of reference; 4) the rate of change information for the data; and 5) event information (published app., para. 0030). The systems and displays of the applicant's invention map the operator's cognitive needs into the graphical elements of the display. Information displays that, in this intuitive manner, show the quantitative, qualitative, temporal, and relational information that clinicians need are not found in the prior art (published app., para. 0006).

For example, Woodring et al disclose earlier generation ventilation displays. In the displays of Woodring et al, only alphanumeric or signal waveform representations of ventilator and/or patient parameters are presented, with alphanumeric representations predominating. The parameters are not presented in relation to each other, nor are they pictorially represented in a way that cognitively presents their physical relationship to the system they are modeling. In particular, the displays of Woodring et al do not present any visual memory cues, intuitive graphical representations, or perceptual diagrams of the ventilator and/or patient information. The displays of Woodring et al therefore lack much of the unique information that is provided by the applicant's invention. This type of system for displaying physiologic data to physicians in critical care or other medical settings forces physicians to perform a great deal of cognitive work in order to interpret and act on the data (published app., para. 0031). This need for cognitive

work is a significant source of both human error and delay in patient treatment. It is this problem that is solved by the applicant's invention.

As an example of how the applicant's invention solves the problems of the earlier generation prior art displays, bellows object 158 visually displays the volume of air being pushed into the patient's lungs in a manner that reflects the physician's mental model of this process. This allows the physician to intuitively understand the pathology of the process and rapidly determine what adjustments to the ventilator are needed to correct problem states. The cognitive steps needed for this process are thereby minimized, consequently minimizing the opportunities for errors and/or delays in taking corrective action. Similarly, the inspiration and expiration processes of the patient are depicted by the closing and opening, respectively, of valve 174 on the display, intuitively reflecting the physician's mental model of the patient's airway.

In order to clarify the advantages of the applicant's invention, the applicant has amended independent claims 15, 21, and 23 to recite that the applicant's data object is designed to minimize the cognitive steps required by a user to interpret the information and that it includes at least one visual memory cue, intuitive graphical representation, or perceptual diagram of certain information. The applicant believes that these recitations make it clear that the applicant's invention is not anticipated by the earlier generation alphanumeric and signal waveform displays found in the prior art. For this reason, claims 15, 21, and 23, as amended, are not anticipated by the display of Woodring et al, or by any other prior art, and are thus in condition for allowance.

Further, as disclosed and claimed, the applicant's data object is "divided into" two objects, one for the volume ventilator and one for the pressure ventilator. The ability to display simultaneously both the volume and pressure ventilation data, and in particular to show the relationship between the two ventilation processes, is not present in the displays of Woodring et al. The displays of Woodring et al allow presentation of either volume or pressure ventilation information, but not both simultaneously, and further provide no emergent information about the relationship between the two. In fact, a stated goal of Woodring is to attempt to reduce errors "by providing a single interface and only providing those specific parameters to [a particular] mode of operation" (Woodring et al, col. 13, lines 39-46). Woodring et al thus actually teaches away from the display of the applicant. For these additional reasons, claims 15, 21 and 23 are not anticipated by the display of Woodring et al and are thus in condition for allowance.

Because claim 22 depends from currently amended independent claim 21, which is not anticipated by Woodring et al and is now in condition for allowance, claim 22 is also in condition for allowance. Similarly, because claims 24 and 25 depend from currently amended independent claim 23, which is not anticipated by Woodring et al and is now in condition for allowance, these claims are also in condition for allowance.

## II. Rejections under 35 U.S.C. 103(a)

Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al in view of U.S. Pat. No. 5,931,960 (Gilmore et al). Claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al in view of U.S. Pat. No. 6,024,089 (Wallace et al). Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al in view of known techniques in the art of the invention.

Because claims 16, 17, and 18 depend from currently amended independent claim 15, which is now in condition for allowance, these claims are now also in condition for allowance. The applicant has further added new claims 26-31, which also depend from claim 15 and are therefore similarly in condition for allowance.

In addition, claims 16-18 are allowable because the combination of Woodring et al with the cited references does not enable the applicant's claimed invention. As discussed above, Woodring et al disclose earlier generation ventilation displays wherein only alphanumeric or signal waveform representations of ventilator and/or patient parameters are presented. Neither Woodring et al, nor any of the other cited references, disclose use of visual memory cues, intuitive graphical representations, or perceptual diagrams of the ventilator and/or patient information that are designed to minimize the amount of cognitive work required in order to interpret and act on the data, as is required by the application's invention and claims. The combination of Woodring et al with the cited references does not therefore render the applicant's invention unpatentable. For this additional reason, claims 16-18 are patentable over Woodring et al in view of the cited references or any other prior art and are thus in condition for allowance.

Further, in regard to claim 16, the applicant's series of pressure ventilation horizontal lines 164 are not used solely to show the direction of air flow, as are the earlier generation +/- symbols of Gilmore et al. Rather, the lines of the applicant's display are used to depict the direction (in the form of arrow heads), volume (via the number of solid lines), and unused

volume (via the number of dashed lines) of air flow in a manner that intuitively communicates, within a single graphical object, the complete relationship between the settings of the ventilator and the air flow to the patient (published app., para. 0161). The pressure ventilation arrows of the applicant are therefore not merely a “design choice”, but rather contribute to the solution provided by the applicant’s invention by minimizing the cognitive steps needed by the user to identify and correctly deal with pressure ventilation problem states. To clarify this point, the applicant has amended claim 16 to indicate that the horizontal arrows are used to portray the volume of air flow to the patient, not just the direction. Therefore, neither the +/- symbols of Gilmore et al, nor any prior art arrows that depict direction in a display, supply the element recited in claim 16. For this additional reason, claim 16 is patentable over Woodring et al in view of Gilmore et al or any other prior art and is thus in condition for allowance.

Similarly, the horizontal and vertical scales recited by claims 17 and 18 are not merely design choices, but have been specifically selected for their ability to communicate various emergent features beyond the raw data obtained from the ventilator and/or patient. In particular, the horizontal scales of claim 17 are used not just for displaying respiration rate, breath cycle time, inspiration time and expiration time, but also for displaying information concerning the relationship between these parameters. To clarify this point, the applicant has amended claim 17 to recite this relationship. Similarly, the vertical scale of claim 18 may be used for displaying information concerning the relationship between PIP, MAP, and PEEP. The choice of these particular graphical representations thus specifically contributes to the solution provided by the applicant’s invention. For this additional reason, claims 17 and 18 are patentable over Woodring et al in view of Wallace et al, known techniques in the art of the invention, or any other prior art and are thus in condition for allowance.

### III. Rejections under 35 U.S.C. 112, second paragraph

Claim 16 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 16 has now been amended to clarify that the object display is the subject of the element recited in this claim. The applicant therefore believes that claim 16, as amended, is now in condition for allowance.

#### IV. Conclusion

Claims 15-18, 21, and 23 have been amended to clarify the scope of the applicant's invention. New claims 26-31 have been added to further define the scope of the applicant's invention. The applicant respectfully submits that claims 15-18 and 21-31 are now in condition for allowance.


For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited. However, should there remain unresolved issues, it is respectfully requested that the Examiner telephone Norma E. Henderson, Applicant's Attorney, at 603-225-4334 so that such issues may be resolved as expeditiously as possible.

Respectfully Submitted,

Hinckley, Allen & Snyder LLP

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Date

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